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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/236,402	05/02/1994	RICHARD T. DEAN	DITI-107	3548

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EXAMINER
RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
1654	

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48

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/236,402	DEAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-8,11-17,19-21 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-8,11-17,19-21 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 May 1994* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

The declaration filed June 23, 2003 and signed by Inventors Dean and Lister-James is noted. The copy of the declaration signed by Inventor McBride has not been received by the time it became necessary to prepare this Office action. However, had it been received, the declarations would not satisfy the requirement for a new oath or declaration set forth in paragraph 2 of the previous Office action and repeated above. This is because the declaration filed June 23, 2003 refers to amendments which contain new matter. Such amendments at least include those filed on April 14, 1998 and on August 24, 2001 and contain amendments to claims 34-37 which were the subject of a rejection under 35 U.S.C. 112, first paragraph, in paragraph 6 of the previous Office action. As set forth in MPEP 602 in the section under the heading "New Matter Issues", a declaration is improper if it refers to an amendment which contains new matter.

The examiner suggests that the new oath or declaration required above not include any reference to any amendments filed in this application.

2. The Sequence Listing filed June 23, 2003 has been approved.

3. The disclosure is objected to because of the following informalities: In the amendments to the list beginning at page 12, line 3, and to Table 1 at page 19, the periods which occurred before "Hcy." were changed to commas without any markings as required by 37 CFR 1.121. It is not clear if these changes were intentional, and if so, it is not clear what effect the changes were intended to have on the meaning of the chemical formulas. In the amendment to the paragraph beginning at page 24, line 21, line 5 of the amendment, "filed" should be changed to "field". Appropriate correction is required.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-8, 11-17, 19, and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 5,849,261. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '261 patent anticipate instant claims 1-3, 6-8, 11-15, 19, and 38. The '261 patent claims synthetic receptor-binding VIP, which corresponds to

Applicants' specific binding compound, linked to a technetium chelating moiety, which corresponds to Applicants' radiolabel complexing moiety. The '261 patent claims a technetium chelating moiety which has Applicants' formula I (see claims 15 and 18 of the '261 patent). The '261 patent claims kits for preparing the compounds, which include a reducing agent. With respect to instant claims 11-13, note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art. With respect to instant claims 12 and 16, while the '261 patent does not claim a stannous ion reducing agent, it would have been obvious to one of ordinary skill in the art to use a stannous ion reducing agent in the claimed invention of the '261 patent because stannous ion reducing agents are routinely used in the art to prepare scintigraphic imaging agents labeled with technetium. With respect to instant claims 17 and 38, while the '261 patent does not claim a method for imaging a site, the '261 patent does claim scintigraphic imaging agents comprising radiolabeled compounds (see, e.g., claim 19), and it would have been obvious to one of ordinary skill in the art to use a claimed compound for its claimed intended purpose.

The terminal disclaimer filed June 23, 2003 was not approved because it was not signed.

5. The effective filing date of instant claims 1-3, 6-8, 11-17, 19-21, and 38 is deemed to be May 2, 1994, the filing date of the instant application. The instant claims are deemed not to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 07/807,062 (now U.S. Patent No. 5,443,815) because the parent application, under the test of 35 U.S.C. 112, first paragraph, (1) does not disclose a molecular weight range for the specific binding compound of less than 10,000 daltons; (2) does not disclose a radiolabel complexing moiety having formula I or II; (3) does not disclose R^1 being a lower alkyl or a covalent linkage to the

compound; (4) does not disclose Z linked to a NR^3R^4 group, an amino acid, or a peptide comprising 2 to 10 amino acids; (5) does not disclose R^2 being H, a lower alkyl, or a covalent linkage to the compound; (6) does not disclose Y linked to an amino acid or a peptide comprising 2 to 10 amino acids; (7) does not disclose linkage of the moiety to the compound through R^1, R^2, or a sidechain group of $(amino\ acid)^1$ or $(amino\ acid)^2$; (8) does not disclose the radiolabel complexing moieties of instant claim 3; (9) does not disclose a ferrous ion reducing agent as is recited in instant claims 12 and 16; and (10) does not disclose a compound which binds to a thrombus site or a site of an infection.

Note that any claim which is not directed solely to subject matter adequately disclosed in the parent application is not entitled to the benefit of the filing date of the parent application. Because the instant claims are not entitled to the benefit of the filing date of parent application 07/807,062, and because the parent application has a different inventorship than the instant application, the patent which issued based upon parent application 07/807,062 is available as prior art against the instant claims under 35 U.S.C. 102(e). This result is consistent with the statutory and case law as shown by MPEP 201.11(VI) under "When Not Entitled To Benefit Of Filing Date", and also by Chester v. Miller, 15 USPQ2d 1333 (Fed. Cir. 1990).

On the basis of their priority claims, U.S. Patent Nos. 5,849,260 and 5,654,272 are available a prior art under 35 U.S.C. 102(e) against the instant claims regardless of whether Applicants' claims are entitled to the benefit of the filing date of parent application 07/807,062. It is noted that while U.S. Patent No. 5,849,260 is a continuation of a continuation of application serial no. 07/653,012, and U.S. Patent No. 5,654,272 is a division of the same application serial no. 07/653,012, the specifications of the two patents are not the same. Because there is at least

one common inventor among this application and the two patents, and because the application and the two patents have the same assignee, Applicants are in the best position to clarify this discrepancy and make any necessary corrections. Until any such necessary corrections are made, the examiner will assume that each patent is entitled to the benefit of its earliest claimed priority date.

It should also be noted that the filing of a terminal disclaimer over a patent has no effect on rejections under 35 U.S.C. 102 or 103 based upon the availability of the patent as a prior art reference. See MPEP 804(III).

Applicants did not traverse the effective filing date analysis made in the previous Office action and repeated above in their response filed June 23, 2003. Also, the correction to the priority claim in U.S. Patent No. 5,849,260 referred to by Applicants at page 20 of the response has not occurred as of the time of this Office action.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-3, 6-8, 11-17, 19, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al (U.S. Patent No. 5,443,815). Dean et al '815 teaches specific peptides in Table I which comprise a specific binding compound (e.g., the GRGD of SEQ ID NOS:2 and 3 or the RALVDTLK of SEQ ID NO:4) and a radiolabel complexing moiety (e.g., the GGC or SEQ ID NO:2 or the maGGG and PenGGG of SEQ ID NOS:3-4). The peptides are labeled with Tc-99m (see Example 2). More generally, the peptides can be labeled by incubation of the peptide in the presence of a stannous chloride reducing agent, and a kit can be provided for preparing the radiolabeled peptide by a reduction method. See, e.g., column 4, line 45 - column

5, line 5. With respect to claims 11-13, note that process limitations do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art. The radiolabeled peptides are used for imaging a mammalian body (see, e.g., the Abstract and column 5, lines 13-43).

8. Claims 1-3, 6-8, 11-17, 19, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 93/10747. The WO Patent Application '747 contains the same disclosure as Dean et al (U.S. Patent No. 5.443,815) applied above, and anticipates the claims for the same reasons set forth above.

9. Claims 1-3, 6-8, 11-17, 19, 20, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al (U.S. Patent No. 5,849,260). Dean et al '260 teaches specific peptides in the Table at columns 11-12 which comprise a specific binding compound and a radiolabel complexing moiety. The peptides are labeled with Tc-99m, either through use of a stannous chloride reducing agent or through ligand exchange, and kits for preparing the radiolabeled peptides are provided. The peptides are used to image thrombus sites in a mammalian body. See, e.g., the Abstract; column 9, lines 14-46; and Example 2. The Table teaches peptides GRGDGGC, maGGRGDF, mmpGGGRGDF, and GRGDGGGGC in which the GGC, maGG, mmpGGG, and GGGC residues, respectively, correspond to Applicants' radiolabel complexing moiety and the remaining residues correspond to Applicants' specific binding compound. Dean et al '260 also teaches, e.g., the fourth compound of the Table, in which the C-terminal GCamide residues correspond to a peptide comprising 2 amino acids attached to the carbonyl group of Applicants' Z residue, the GGGC residues correspond to Applicants' radiolabel complexing moiety of formula I, and the remainder of the compound corresponds to Applicants' specific

binding compound. Note that Applicants' claims do not contain any limitations which exclude amino acids containing a thiol group from forming part of, e.g., the specific binding compound, the amino acid or peptide attached to the carbonyl group of Z, or the one or more amino acids which can link the peptide and the moiety.

10. Claims 1-3, 6-8, 11-17, 19, 21, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by the WO Patent Application 93/17719. The WO Patent Application '719 teaches specific peptides at pages 20-22 and 24 which comprise a specific binding compound and a radiolabel complexing moiety. The peptides are labeled with Tc-99m, either through use of a dithionate, stannous, or ferrous reducing agent or through ligand exchange, and kits for preparing the radiolabeled peptides are provided (see, e.g., page 14, line 24 - 15, line 6). The peptides are used to visualize sites of inflammation, including abscesses and sites of occult infection (see, e.g., the Abstract and page 16, lines 9). With respect to the peptide, e.g., at page 20, line 17, of the WO Patent Application '719, the residues $(VGVAPG)_3$ correspond to Applicants' specific binding compound (see also page 12, line 7); the residues GGGC correspond to Applicants' radiolabel complexing moiety of formula I; and the residues GCamide correspond to a peptide comprising 2 amino acids lined to the carbonyl group of Applicants' Z.

11. Claims 1-3, 6-8, 11-17, 19, 21, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean et al (U.S. Patent No. 6,017,510). Dean et al '510 is the U.S. equivalent of the WO Patent Application '719 applied above, and anticipates the claims for the same reasons set forth above.

12. Claims 1, 2, 6-8, 11-17, 19, 21, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Dean (U.S. Patent No. 5,552,525). Dean '525 teaches specific peptides in the

Table at columns 10-11 which comprise a specific binding compound and a radiolabel complexing moiety. The peptides are labeled with Tc-99m, either through use of a stannous chloride reducing agent or through ligand exchange, and kits for preparing the radiolabeled peptides are provided (see, e.g., column 8, lines 21-65). The peptides are used to visualize sites of inflammation and infection (see, e.g., the Abstract and column 6, lines 52-62). With respect to the peptide, e.g., at claim 20 of Dean '525, the N-terminal residues CG correspond to a peptide comprising 2 amino acids attached to an amino group of Applicants' Y group, the residues CGG correspond to Applicants' radiolabel complexing moiety of formula II, and the remaining residues correspond to Applicants' specific binding compound (see also claim 7 of Dean '525).

13. Claims 1, 2, 6-8, 11-17, 19, 20, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamora (U.S. Patent No. 5,556,609). Zamora '609 teaches peptides comprising the sequence YIGSR, which targets cells containing receptors for YIGSR such as platelets which occur at thrombosis sites, and also comprising a metal ion-binding domain. See, e.g., the Abstract; column 4, lines 50-64; and column 7, lines 54-63. In Example 7, the metal ion-binding domain is CDG, which corresponds to Applicants' Formula II, or GRC, which corresponds to Applicants' Formula I. In Example 7, the metal ion-binding domains are linked to the YIGSR sequences through one or more amino acids. The peptide in Example 7 labeled with Tc-99m in the presence of a stannous tartrate reducing agent. Labeling kits are also taught (see, e.g., column 7, lines 64-66). With respect to instant claim 13, process steps do not impart patentability to product-by-process claims where the product is otherwise anticipated by or obvious over the prior art.

14. Claims 1-3, 6, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 90/10463. The WO Patent Application '463 teaches reagents for and a method of imaging inflammation caused by infection. The reagents comprise a labeled recognition agent, where the recognition agent is capable of interacting selectively with activated leukocytes at the inflamed tissue sites. A preferred chelating compound for labeling the recognition agent is a N_3S metal chelating compound. A preferred recognition agent is a chemotactic peptide. The radiolabel can be Tc-99m. Also taught is a peptide recognition agent linked through a Gly_{1-5} spacer to a cysteine residue. Diagnostic kits including instructions for labeling are also taught. See. e.g., the Abstract; page 3, lines 7-11; page 4, line 16 - page 5, line 21; page 7, lines 3-9; page 11, line 34 - page 13, line 3; page 26, line 16 - page 27, line 3; page 38, lines 28-35; page 39, line 26 - page 41, line 5; and claims 11, 12, 17, and 29-33.

15. Claims 1, 2, 6-8, 11-17, 19, 21, and 38 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 90/10463 as applied against claims 1-3, 6, 19, and 21 above, and further in view of Fritzberg et al (U.S. Patent No. 4,965,392). The WO Patent Application '463 does not teach a chemotactic peptide recognition agent labeled with N_3S metal chelating compound which is used to complex Tc-99m. Fritzberg et al '392 teaches a N_3S metal chelating compound used to label a wide variety of polypeptide and carbohydrate compounds. Fritzberg et al '392' preferred chelating compound is mercaptoacetylglycylglycylglycine, which is labeled with Tc-99m in the presence of a stannous ion reducing agent. See, e.g., column 6, line 35 - column 7, line 3; column 8, lines 24-29; and Examples I-IIIb, IV, and V. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the mercaptoacetylglycylglycylglycine chelating compound of Fritzberg et al '392 to label the

chemotactic peptide recognition agents of the WO Patent Application '463 because the mercaptoacetylglycylglycylglycine chelating compound of Fritzberg et al '392 is a species of the N_3S metal chelating compounds generically disclosed by the WO Patent Application '463, because the mercaptoacetylglycylglycylglycine chelating compound of Fritzberg et al '392 is disclosed as being useful in labeling a wide variety of polypeptide and carbohydrate compounds and therefore would have been expected to be useful in labeling the chemotactic peptide recognition agents of the WO Patent Application '463, because Fritzberg et al '392 teach that their chelating compounds have the benefit of being able to accurately direct a radionuclide to a preselected site to reduce background radiation, to reduce dosage, to minimize background for in vivo imaging, and to minimize undesirable side effects (see column 1, lines 30-38), and because Fritzberg et al '392's chelating compound would permit labeling of the WO Patent Application '463's chemotactic peptide recognition agents with Tc-99m, which the WO Patent Application '463 discloses to be a useful radionuclide.

16. Claims 1-3, 6, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by the Plank et al article (Bioconj. Chem., Vol. 3, pages 533-539). The Plank et al article teaches compound 1b (Figure 1), in which the C-terminal Gly-Gly-Cys residues correspond to Applicants' radiolabel complexing moiety of formula I, and the N-terminal galacotside-polylysine-Gly residues correspond to Applicants' specific binding compound, and the remaining residues correspond alternatively to portions of Applicants' radiolabel complexing moiety, to Applicants' specific binding compound, or to the amino acids linking the peptide and the moiety. See also the Abstract.

17. Applicant's arguments filed June 23, 2003 have been fully considered but they are not persuasive.

The rejection under 35 U.S.C. 102(a) based upon Dean et al (U.S. Patent No. 5,443,815) is maintained. The declaration by Inventor Dean referred to at pages 21-22 of Applicants' Remarks has not yet been received. However, even when it is received, it will not overcome the rejection because it will not show that the subject matter of the reference relied upon in the rejection is not "by another". As summarized by Applicants in the remarks, the declaration will show that the subject matter of the reference relied upon in the rejection was conceived by Inventor Dean. However, the inventorship of the instant application is Inventor Dean plus Inventors Lister-James and McBride. This still constitutes "by another". See MPEP 2136.04 for a discussion of the meaning of the statutory phrase "by another". For analogous reasons, the rejection over the WO Patent Application 93/10747 will also be maintained.

The rejections based upon Dean et al (U.S. Patent No. 5,849,260) and Dean (U.S. Patent No. 5,552,525) will also be maintained. These references do not have the identical inventive entity as the instant application, and are therefore "by another". Again, see MPEP 2136.04.

The rejection based upon Dean et al (U.S. Patent No. 5,561,220) set forth in the previous Office action is withdrawn for the reasons given by Applicants at page 24 and at page 25, first full paragraph, of their response.

The rejection based upon the WO Patent Application 93/17719 is maintained. Once the executed declaration by Lister-James is submitted, the examiner will accept its statements with respect to peptides comprising a CGC motif, i.e. the examiner will not argue that such peptides anticipate the instant claims. However, the WO Patent Application '719 teaches peptides which

comprise a GGC or a CGG motif and which do not comprise a CGC motif. See, e.g., page 21, lines 3 and 5, and page 24, line 4. These peptides will continue to anticipate Applicants' claims.

The rejection based upon Dean et al (U.S. Patent No. 6,017,510) is maintained for the same reasons set forth above with respect to the WO Patent Application '719. Applicants are correct that Dean et al '510 is the equivalent of the WO Patent Application '719 rather than the WO Patent Application 747. The examiner apologizes for any confusion this error may have caused.

The rejection based upon Zamora (U.S. Patent No. 5,556,609) is maintained. Applicants distinguish Zamora on the basis that Zamora's compounds of Example 7 contain two biological function domains and two metal ion-binding domains, whereas Applicants' claims are limited to reagents having one specific binding compound and one radiolabel complexing moiety. However, in order to demonstrate that Applicants' claims are limited to reagents having one specific binding compound and one radiolabel complexing moiety, Applicants point to indefinite articles found in the specification, whereas patentability must be based upon claimed differences over the prior art. The "comprising" language found in Applicants' claims, e.g., at claim 1, line 2, permits the presence of plural specific binding compounds and plural radiolabel complexing moieties. [The examiner agrees with Applicants' analysis that the single letter sequence in Example 7 of Zamora is probably the correct sequence, and also agrees that this sequence discrepancy in Zamora does not affect the basis of the rejection.]

The rejection over the WO Patent Application 89/11877 is withdrawn for the reasons given by Applicants.

The anticipation rejection based upon the Morrison et al article (FEBS Letters, Vol. 214, pages 65-70) is withdrawn. The prior art of record does not establish that the first nine residues of LHRH will specifically bind to the LHRH receptor, and therefore there is no case of prima facie anticipation.

The rejections based upon the WO Patent Application 90/10463 and upon the WO Patent Application 90/10463 in view of Fritzberg et al (U.S. Patent No. 4,965,392) are maintained. The WO Patent Application '463 does disclose reagents comprising two functionally distinct portions, namely a specific binding compound, i.e. the recognition agent which is bound to group Z at page 12, lines 22-24, and a radiolabel complexing moiety, i.e. the moiety having the structure at page 12, lines 1-10. Applicants discuss how the compound of Example 1 of the reference fails to anticipate the instant claims, with which discussion the examiner agrees. However, the disclosure of the reference is not limited to the single compound of Example 1, and Applicants have not explained how the sections of the reference actually relied upon by the examiner fail to anticipate the instant claims. Regardless of the disclosure at page 11, line 34 - page 13, line 3, of the WO Patent Application '463, the disclosure at page 38, lines 28-35 in and of itself anticipates the instant claims. This section of the reference teaches f-M-L-F-spacer-C where the spacer can be a chain of 1-5 glycines. Given the small number of species encompassed by the genus of 1-5 glycines, and given the specific naming of the endpoint of 5 glycines, one of ordinary skill in the art would immediately envisage chains of 3, 4, and 5 glycines. These compound f-M-L-F-spacer-C with a spacer of 3, 4, or 5 glycines has the same structure and function as Applicants' claimed reagents, and therefor anticipates Applicants' claimed reagents. Note that a mere difference in descriptive terminology does not impart

patentability to Applicants' claims as long as the compound of the prior art has the same structure as Applicants' claimed compound. See In re Skoner, 186 USPQ 80, 82 (CCPA 1975). With respect to the obviousness rejection, the prior art suggestion or motivation to combine the references is set forth at page 18, lines 1-15, of the previous Office action and repeated above.

The rejection based upon the Plank et al article (Bioconj. Chem., Vol. 3, pages 533-539) is maintained. As set forth in the effective filing date analysis in paragraph 5 above, Applicants' claims are not entitled to the benefit of the filing date of parent application 07/807,062. Accordingly, the Plank et al article is available as prior art against the instant claims under 35 U.S.C. 102(b). It is not possible to antedate a reference which is available as prior art under 35 U.S.C. 102(b). See 37 CFR 1.131(a)(2). If Applicants want their claims to be entitled to the benefit of the filing date of parent application 07/807,062, Applicants must limit the subject matter recited in the claims exclusively to that disclosed in the parent application. See, e.g., MPEP 201.11(VI) under "When Not Entitled To Benefit Of Filing Date", second paragraph.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Art Unit 1654 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 30, 2003

BRENDA BRUMBACK
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